UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,352	10/08/2003	Kyoji Ogoshi	3190-044	8311

33432 7590 11/02/2007

KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER	
SIMS, JASON M	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,352	OGOSHI, KYOJI	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, 8/20/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 8/20/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group.

Claims 25-26 are the current claims hereby under examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) for the date of 10/8/2003, which has been granted. The certified copy has been filed on 12/28/2006. Receipt is acknowledged and the papers have been placed of record in the file.

Claim Objections

The objections to claim 25 have been withdrawn in view of applicant's amendment to the claims.

Claim Rejections - 35 USC § 112

Applicant's arguments, filed 8/20/2007, with respect to the rejection of claims under 35 USC 112 second have been fully considered and are persuasive because of applicant's amendments to the claims. Therefore the rejection has been withdrawn.

The following is a newly applied rejection that has been necessitated by amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 contains the wording "a statistically significant probability of prolonging the cancer patient's survival based on the amino acids encoded at the positions of the JLADQB1* gene," etc. wherein "based on the amino acids encoded" has been deemed as vague and indefinite. It is unclear as to what the exact relationship is between the dependency of the amino acids encoded and the probability of prolonging the cancer patient's survival. It appears that a cancer treatment may be determined based on the amino acids encoded, but the instant claim reads that the probability of prolonging the cancer patient's survival is based on the amino acids encoded. In other words it not clear as to what relationship is intended by the phrase "based on" – i.e. what parameters and/or other decisions are included such that one can determine whether

survival or treatment can be "based on" encoded amino acids? Clearer claim wording is required.

Claim 26 is rejected as being dependent from a rejected claim.

Claim Rejections - 35 USC § 103

The following rejection is being maintained:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (J. Clinical Oncology, vol. 19, pp. 1279-1287, 2001) in view of Lee et al. (Gastroenterology, vol. 111, pp. 426-432, 1996) and further in view of Santamaria et al. (US P/N 5,972,604).

The claims are directed to a method for determining treatments for a cancer patient comprising determining what amino acids are encoded by one or more of a

number of positions of the HLA DQB1 *gene, determining what amino acids are encoded by one or more of a number of positions of the DRB1 *gene, determining what amino acids are encoded by one or more of a number of positions of the DPBI *gene, and correlating the amino acids encoded at the positions with a cancer treatment having the greatest statistically significant probability of prolonging the cancer patient's survival, wherein the cancer treatment comprises immunotherapy, chemotherapy, resection, or a combination thereof.

Davies et al. teach a method for evaluating cancer treatments based on genotyping polymorphic genes of patients receiving cancer therapy and correlating the survival results of patients containing a specific polymorphic gene with appropriate cancer treatment regimens (see abstract, p. 1279). The reference teaches that the polypeptide encoded by polymorphic genes of Glutathione S-transferase, i.e., namely theta (GSTT1) and mu (GSTM1), affect the cytotoxicity of chemotherapeutic drugs. Experimental DNA typing data of Glutathione S-transferase polymorphic genes were obtained from a patient population of children with acute myeloid leukemia or AML (see Table 1 and GST Genotyping, p. 1280) receiving chemotherapy (see Chemotherapy Treatment Regimen). GSTT1 and GSTM1 genotype outcome differences in overall survival, disease-free survival and relapse-free survival were statistically analyzed (see Statistical Analysis, p 1280, Figures 1-5, pp.1281-1282, and Tables 2-3, pp. 1282-1283) and further lead to the conclusion that children lacking GSTT1 had greater toxicity and reduced survival rate after chemotherapy for AML compared with children with at least

one GSTT1 allele, wherein the genotype might be of useful in selecting appropriate chemotherapy regimens for children with AML (see last paragraph of p. 1284).

Davies et al. does not teach any association of HLA class II genes with any cancer. However, the references of Lee et al. (see line 1-2, col. 1, p. 426) and Santamaria et al. (col. 3, lines 1-67, col. 4, lines 1-7, col. 9, lines 60-68, and col. 10, lines 1-16) teach HLA Class II genes are associated with several cancers, including the DRB1, DQB1, and the DPB1 genes. Namely, "HLA-DQB1*0310 is more common in Caucasian patients with gastric adenocarcinoma than noncancer controls" (Lee et al. see conclusions, p. 426).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to use the genotyping methods of Davies et al. or Lee et al. or Santamaria et al. along with the statistical methods of Davies et al. to identify HLA Class II polymorphic genes of patients receiving cancer therapy and correlating the survival results of HLA Class II genotype with appropriate cancer treatment regimens. Because of the extensive cancer polymorphic genotyping of Lee et al. and Santamaria et al. and the productive results of cancer polymorphic genotyping of Davies et al., one would have been motivated by Davies et al. who states that "This study shows that pharmacogenetic factors can influence the outcome of therapy, and particularly dose-intensive therapy" to combine the references.

Response to arguments:

Applicant's arguments 8/20/2007 have been fully considered but they are not persuasive.

Applicant alleges that Davies et al. does not teach or fairly suggest the steps of method claim 25. Applicant specifically states that the studies conducted in Davies et al. involved intensively timed chemotherapy treatments provided to children with acute myeloid leukemia only and further states that Davies et al. makes no mention of treatments involving immunotherapy or resection.

Applicant's allegations are not found persuasive as claim 25 does not necessitate that a prior art reference mention treatments involving immunotherapy or resection. Claim 25 comprises the open-ended language wherein the treatment comprises immunotherapy, chemotherapy, resection, or a combination thereof. Therefore the mention of chemotherapy treatments reads on treatment, which comprises chemotherapy.

Applicant alleges that Lee et al. and Santamaria et al. do not alone, or in combination, overcome deficiencies in Davies et al. and specifically state that there is no indication how one could determine the optimal treatment for such patients relying on the disclosure of Davies et al.

Applicant's allegations are not found persuasive because claim 25 is not drawn to determining the optimal treatment, but is drawn to determining a cancer treatment having a **statically significant probability** of prolonging the cancer patient's survival. Therefore, any treatment that has a high chance for prolonging the cancer patient's survival, no matter for how long, reads on claim 25. Lee et al. does draw an association between HLADQB1 gene and cancer and specifically states in the summary that identification of the mechanism associating HLA-*DQBI*0301* with gastric cancer could

ultimately help target individuals most likely to benefit from cancer screening and prevention programs and could suggest novel therapeutic strategies for cancer immunoprevention. Therefore, Lee does provide the motivation for combining the analysis as taught by Davies et al. with the analysis between HLADQB1 gene and cancer taught by Lee et al. for determining cancer screening and prevention programs and could suggest novel therapeutic strategies for cancer immunoprevention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Marjorie A. Moran/

Marjorie A. Moran
SPE, AU 1631
10/29/07